

Remarks

Applicants thank the Examiner for the courtesy extended to their representatives, Jane Gunnison, Shilpa Patel and Pamela Salkeld in the granting of an interview. The purpose of the interview was to discuss with the Examiner a strategy for expediting the granting of a patent so that patent term extension under 35 U.S.C. § 156 would be maximized for a particular monoclonal antibody. To expedite the granting of a patent, applicants have herein cancelled claims that they intend to prosecute in a continuation application. No inference is intended with respect to the patentability of claims not pursued in this application. The sole purpose in submitting the claims presented herein is to expedite the grant of a patent to maximize patent term extension.

Applicants have cancelled claims 1-19, 21, 22 and 28, without prejudice. Applicants expressly reserve the right to pursue any cancelled subject matter in subsequent applications that claim benefit from this application.

Applicants have amended claims 23-27 and 29-32 to improve their form and to conform claim dependencies to the amendments herein. Applicants have added claims 34-150 to more particularly point out and distinctly claim the subject matter that they wish to prosecute in this application. Support for these claims is found throughout the application.

Specifically, support for claims 34, 35, 40 and 43 may be found in claims 1, 2 and 14, as filed. Support for claim 36 may be found in claims 1, 2 and 9, as filed. Support for claim 37, 41 and 44 may be found in claims 1, 2 and 11, as filed. Support for claim 39 may be found in claims 1, 2 and 16, as filed. Support for claims 38, 42 and 45 may be found throughout the application, for example at page 42, line 29 to page 43, line 11. Support for claims 46, 50 and 51 may be found in claims 1, 2 and 16, as filed. Support for claims 47-49 may be found throughout the application, for example at page 75, line 5. Support for claim 52 may be found in claims 1 and 15, as filed. Support for claim 53 may be found in claims 1, 2 and 10, as filed. Support for claim 54 may be found throughout the application, for example, page 19, line 24 and page 29, line 29 to page 30, line 4. Support for claim 55 may be found in claims 1, 2 and 8, as filed. Support for claim 56 may be found throughout the application, for example at page

28, lines 9-16. Support for claims 57-72 may be found in claims 1, 2 and 12, as filed. Support for claims 73-96 may be found in claim 18, as filed. Support for claims 97-119 may be found in claim 19, as filed. Support for claims 120 and 121 may be found in claims 21 and 22, as filed. Support for claims 122 and 136 may be found in Example III, as filed. Support for claims 123 and claim 137 may be found in Examples III and VIII, as filed. Support for claims 124, 125, 138 and 139 may be found in Example IV, as filed. Support for claim 126 and 140 may be found in Examples VII and VIII, as filed. Support for claims 127 and 141 may be found in Example XI, as filed. Support for claims 128 and 142 may be found in Example XIII, as filed. Support for claims 129 and 143 may be found in Example XIV, as filed. Support for claims 130 and 144 may be found in Example XVI, as filed. Support for claims 131 and 145 may be found in Example XI, as filed. Support for claim 132 may be found in claim 23, as filed. Support for claim 133 may be found in claim 24, as filed. Support for claim 134 may be found in claim 25, as filed. Support for claim 135 may be found in claim 26, as filed. Support for claims 146 and 147 may be found in claim 30, as filed. Support for claim 148 may be found in claim 28, as filed. Support for claim 149 may be found in claim 27, as filed. Support for claim 150 may be found in claim 28, as filed.

None of these amendments adds new matter. Upon entry of the amendments, claims 20, 23-27 and 29-150 will be pending. Of those, claims 20, 23-27, 29-33, and 122-150 are pending but withdrawn as being directed to a non-elected invention. The withdrawn claims are available for rejoinder, if appropriate, upon allowance of claims undergoing examination. Claims 34-121 are pending and under examination.

Withdrawn Claims

The Office Action incorrectly states that claims 20 and 23-32 are withdrawn from further consideration pursuant to 37 C.F.R. § 1.142(b) as being drawn to a non-elected invention. Applicants note, to correct the record, that claims 20 and 23-33 are the withdrawn claims.

Claim Objections

Claims 7-14, 18-19, 21 and 22 stand objected to under 37 C.F.R. § 1.75(c) for improper multiple dependent form. Applicants note that claims 21 and 22 are not multiple dependent claims. Applicants' cancellation of the objected to claims, without prejudice, however, obviates the objection.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 3-6 stand rejected under 35 U.S.C. § 112, second paragraph, as "indefinite". Applicants' cancellation of those claims, without prejudice, obviates the rejection.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 5-6 and 15-17 stand rejected under 35 U.S.C. § 112, first paragraph, as not enabled. The Examiner asserts that it is unclear if a cell line producing an antibody with the exact chemical identity of the recited monoclonal antibodies are known, publicly available or reproducible and states that a deposit would satisfy the enablement requirement. The Examiner also states that if the recited monoclonal antibodies have been deposited under the provisions of the Budapest Treaty, a declaration or affidavit confirming that and assuring that upon grant of a patent all restrictions on the deposits will be irrevocably removed is required.

Claims 34, 35, 51, 52, 121, 148, 150 and the claims that depend directly or indirectly from those claims refer to monoclonal antibody 2.13.2. Applicants submit herewith the required declaration stating that hybridoma 2.13.2, which produces monoclonal antibody 2.13.2, was deposited under the provisions of the Budapest Treaty on December 12, 2000, and assigned accession number PTA-2788 and that all restrictions on public access to the deposited material will be irrevocably removed upon the grant of a patent on this application.

Claims 3-4 and 17 stand rejected under § 112, first paragraph, as not enabled. Applicants' cancellation of claims 3-4 and 17, without prejudice, obviates the rejection as to those claims.

Rejection Under 35 U.S.C. § 102(e)

Claims 1-6 stand rejected under 35 U.S.C. § 102(e) as "anticipated" by United States patent publication 2003/0165502 (Fujita-Ymanguchi) ("Fujita-Ymanguchi"). The Examiner asserts that the claims recite a chimeric antibody that binds IGF-IR and that Fujita-Ymanguchi "teach[es] a scFv-FC chimeric antibody that binds human IGF-IR". Applicants' cancellation of claims 1-6 obviates the rejection.

Fujita-Ymanguchi refers to a scFv and to a scFv-Fc molecule both of which have murine Fv domains. None of the pending claims refer to antibodies comprising murine variable domains. The pending claims, thus, are novel over Fujita-Ymanguchi. Accordingly, the rejection under § 102(e) should be withdrawn.

Rejections Under 35 U.S.C. § 103(a)

Claims 1-6 stand rejected under 35 U.S.C. § 103(a) as "unpatentable" over United States patent 6,657,103 (Kucherlapati et al.) ("Kucherlapati") in view of Rubini et al., "Characterization of an Antibody That Can Detect an Activated IGF-I Receptor in Human Cancers," *Experimental Cell Res.*, 251, pp. 22-32 (1999) ("Rubini") and over Rubini further in view of International Publication WO 91/09967 (Adair et al.) ("Adair").

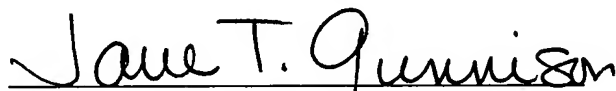
The claims are directed to monoclonal antibodies that comprise certain amino acid sequences or that utilize certain human VH or Vkappa genes. Neither Kucherlapati nor Rubini make any mention of the recited sequences or genes. The cited documents, thus, either alone or combined, cannot render obvious the claimed antibodies. Accordingly, the rejection under 35 U.S.C. § 103(a) should be withdrawn.

Application No. 10/038,591
Response dated October 22, 2004
In Response to June 22, 2004 Office Action

The claims stand rejected over Rubini and Adair insofar as they encompass “humanized” antibodies, i.e., antibodies comprising at least non-human CDRs. None of the pending claims are directed to such antibodies. Accordingly, the rejection under 103(a) over Rubini and Adair is obviated.

In view of the foregoing, applicants request withdrawal of the rejections and allowance of the claims.

Respectfully submitted,

A handwritten signature in black ink that reads "Jane T. Gunnison". The signature is fluid and cursive, with the first name "Jane" and last name "Gunnison" clearly legible.

Jane T. Gunnison (Reg. No. 38,479)

Attorney for Applicants

c/o FISH & NEAVE LLP

1251 Avenue of the Americas

New York, New York 10020-1105

Tel.: (212) 596-9000

Fax: (212) 596-9090